Elements of Data Management
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- Names used in examples are fictional and not based on real people. The use of these fictional names is solely for providing fictional examples in this presentation.
Elements of Data Management

Overview:
• Why is data management so important?
• Who should most be concerned with data management?
• Where does data management fit?
• Organization of data management.
• Highlights:
  • Raw Data.
  • Form Design.
  • In life.
  • Data for submission.
Elements of Data Management

Why is data management so important?
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FDA BIMO inspection findings continue to involve:

• Recordkeeping.
• Inclusion/Exclusion Criteria Issues.
• Informed Consent Issues.
• Dosage Issues.
• IP accountability.
• Analytical Concerns (validation, stability).

Presented by Chrissy J. Cochran, PhD, Director, OBIMO/ORA/FDA
2018 SQA Annual Meeting
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FDA CVM QASR Findings continue to involve:
• Animal accountability, especially for those removed from study.
• Inadequate monitoring/QA.
• Final Study Report does not accurately reflect the raw data.
• Lack of documentation of sample handling from necropsy to freezing (residue studies).
• Test article not able to be reconciled.

Presented by Michelle Kornele, DVM, QA Team Leader and Debi Garvin, MS, RQAP-GLP, GLP/GCP Quality Assurance Specialist
2017 SQA Annual Meeting
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Ultimately why is this so important?

• Our customers, our patients, and their owners are relying on us to be sure our products are safe and effective.
• Good decisions cannot be made with poor data.
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Who in Animal Health should be most concerned with data management?
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FDA BIMO inspections in FY2017 occurred at:

<table>
<thead>
<tr>
<th>Center</th>
<th>CBER</th>
<th>CDER</th>
<th>CDRH</th>
<th>CVM</th>
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<tr>
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<td>31</td>
<td>6</td>
<td>8</td>
</tr>
<tr>
<td>Total</td>
<td>97</td>
<td>1109</td>
<td>302</td>
<td>22</td>
</tr>
</tbody>
</table>

- Total includes numbers from other inspectional areas not performed by CMV and therefore not included (IRB, BA/BE, etc)

Presented by Chrissy J. Cochran, PhD, Director, OBIMO/ORA/FDA
2018 SQA Annual Meeting
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While the majority of BIMO inspections occurred at Clinical Investigator sites, who is responsible for the quality and integrity of the data when submitted to the agency? The Sponsor 😊
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Where does data management fit in?
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Data Management is linked to:

- Data Privacy
- Data Management Plans
- Vendor Management
- Data Acquisition
- Electronic Data Capture
- CRF Completion Guidelines
- Vendor Selection
- Database Validation
- Database Programming
- Laboratory Data Handling
- External Data Transfers
- Presentations at Investigator Meetings
- Training
- Metrics for Clinical Trials
- Assuring Data Quality
- Measuring Data Quality
- Data Storage
- Data Entry Processes
- Medical Coding Dictionary Management
- Safety Data Management and Reporting Serious Adverse Event
- Data Reconciliation
- Database Closure
- Clinical Data Archiving

Selection from SCDM Good Clinical Data Management Practices, October 2009 Edition TOC
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Data Management is linked to DQ & DI

- Data Quality
  - ALCOA
    - Attributable
    - Legible
    - Contemporaneous
    - Original
    - Accurate

- Data Integrity
  - CCAE
    - Complete
    - Consistent
    - Available
    - Enduring

However elements from both lists are inextricably linked. You can’t have quality or integrity without the other.
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Organization of data management
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Who is “Data Management”?  
• Data management is the sum of the processes you wrap around your data to ensure the integrity of your data.

• The centralization of management of these processes may be the responsibility of a group called “Data Management”.

• Clinical and Operational vs Information Services and Infrastructural.
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Who is “Data Management”?  
• Optimally, data management would be an entity involved in study processes, that has a complete investment in the integrity of the data, but separated from the assessment or conclusion of study results.  
• However, it is critical to acknowledge that all individuals involved in studies contribute to the data integrity.
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Who is “Data Management”?  
• In companies with the size and resources, a Data Management unit is often associated with either Statistics or Information Services.

• Based on company size or structure, this may not always be possible. Data management may be more of a process with responsibilities assigned to site personnel, study directors, sponsor personnel, etc.
  • One size does not fit all.
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Who is “Data Management”?

• Data Management ensures data integrity.
• Everyone is responsible.
• All personnel should be trained in detecting data integrity issues.
  • Employees.
  • Temporary Staff.
  • Contractors.
  • Anyone involved in creation, modification, retention or protection of data.
• Everyone should have awareness for detecting issues.
• Everyone should know how to report issues.
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Highlights of how data management facilitates study design, conduct and reporting

• Raw Data.
• Form Design.
• In life.
• Data for submission.
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Raw Data
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Data Management can help determine what is your raw data

- Raw data is defined as the original record (data) which can be described as the first-capture of information, whether recorded on paper or electronically.
  - May include true copies (complete and accurate copies of raw data).
  - Information that is originally captured in a dynamic state should remain available in that state.

Medicines & Healthcare products Regulatory Agency (MHRA) ‘GXP’ Data Integrity Guidance and Definitions; Revision 1: March 201
Determining what is your raw data

- For data to be raw data it must include the metadata.
- Data about data that provides context and meaning.
  - “1” could be a data point.
  - Metadata could include:
    - “g” if it is a weight.
    - “John Smith” to indicate who recorded it.
    - “08 April 2018” to indicate the date recorded.
    - “2” if this was corrected from 2 to 1, reason for change, initials and date of correction (aka – the audit trail).
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Determining what is your raw data

• Static True Copies of Dynamic Raw Data.

• “To enable a GXP compliant record this approach is likely to be demanding in its administration.”
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Form Design
Form Design

- Should ensure forms:
  - Collect the data we need to evaluate the product
  - Collect all the data specified in the protocol.
  - Collect the data as specified in the protocol.
  - Collect the data in a way that will work for the people capturing the data in the field.
  - Are not be limited by design to only please the protocol author.
  - When possible also work for data entry people (art form).
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Form Design

• Should make sense.
  • No “entries by omission”.
  • No entries that require interpretation.
  • No “on the spot calculations” – capture the raw data.
  • PE – HR or RR
  • Exceptions when professional evaluations are performed
    • BRD evaluation scoring

__________ breaths in 15 secs

$X \times 4 = \underline{\text{__________}}$ breaths per minute
Form Design

- Ensure EDC systems do not restrict answers site staff can provide in a way that introduces bias into the clinical study.
  - Can be true for paper also.
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Form Design

Privacy considerations
• Is this data really needed?
• Does the collection of needed data compromise privacy?
• Is the collection of the data acceptable in all countries with study sites?
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In life
Elements of Data Management

In life

• Assist with providing monitoring reports
• QC assistance
• Database and user issue investigations
• Tracking trends
• Tracking study progress.
  • Enrollment success.
  • Completion vs failure to complete ratios and why.
• Supplying data for interim analysis.
  • Gatekeeper for eager statisticians.
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Data for Submission
Elements of Data Management

Determining how to get you the CVM deliverables

- Data file types accepted by e-Submitter:
  - PDF
  - XML
  - XPT
Determining how to get you the CVM deliverables

XML
## Elements of Data Management

### Determining how to get you the CVM deliverables

**XML**

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<th>LastName</th>
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<tbody>
<tr>
<td>U1</td>
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<td>U1</td>
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<tr>
<td>U1</td>
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<td>Chad</td>
<td>Calloway</td>
</tr>
</tbody>
</table>
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Determining how to get you the CVM deliverables

New CVM e-Submitter questions

Describe how the attributes of ALCOA (Attributable, Legible, Contemporaneous, Original, Accurate) were maintained for any non-EDC collected data during the internal handling of the files through the submission of data files to CVM.

Enter each EDC system used to collect data…
Contact Information

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